EXHIBIT 1

PPE Specificate Property PPE Specificate Prope abeling Specification 28 Nov 2014 RMC P15506 Gyndral are TV 154254 Device Heasenain vel: 4. Production

Tension-free Support for Incontinence

GYNECARE TVT™

Tension-free Vaginal Tape

GYNECARE TVT Single Use Device
GYNECARE TVT Reusable Introducer
GYNECARE TVT Reusable Rigid Catheter Guide

GYNECARE TVT™ anordning til engang brug GYNECARE TVT™ indfører til (le/gangsbrug

GYNECARE TVT™ stift guidir g kateter fil flergangsbrug

GYNECARE TVT™ hulpmiddel voor germalig gebruik GYNECARE TVT™ herbruikbere introducer

GYNECARE TVT™ herbruikbare starre kathetervoerder

GYNECARE TVT™ -laite, kertakäyttöinen

GYNECARE TVT™ -sisäänyiejä, kestokäyttöinen GYNECARE TVT™ -katetrinohjain, kestokäyttöinen, jäykkä

Dispositif GYNECARE TV → à usage unique Introducteur réutilisable GYNECARE TV T™ Guide de sonde rigide à utilisable GYNECARE TV T™

GYNECARE TVT" Einmal-Implantet GYNECARE TVT" wieder vorwendbares Einführungsinstrument GYNECARE TVT" wieder verwendbare starre Katheterführung

Συσκευή μιας χρήσης CYNEC4RE TYT™ Επαναχρησι) οποιησιμός εισαγωγεάς GYNECARE/TVT™ Επαναχρησιμε ποιήσιμος άκαμπτος όδηγός καθετήρα GYNECARE/FV.T

Dispositivo nonouso GYNEC/RETVT™ Introduttore riutilizzabile GYNECARE TVT™ Guida rigida riutilizzabile per catetere GYNECARE TVT™

Dispositivo de utilização única GYNECARE TV™ Introdutor reutilizával GyNECARE TVT™ Guia rígido de catater reutilizável GYNECARE TVT™

Sistema para un solo uso GYNECARE TVT™ Introductor reutilizable GYNECARE TVT Guía de catéter rigida reutilizable GYNECARE TVT™

GYNECARE TVT™ produkt för engångsbruk GYNECARE TVT™ återanvändbar införare GYNECARE TVT™ återanvändbar stel kateterguide



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Made in Switzerland © Ethicon, Inc. 2009

Ethicon, Inc. Route 22 West, P.O. Box 151 Somerville, New Jersey 08876-0151 +1-877-ETHICON +1-513-337-6928

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- 11 Principe Super learned in 28 cNote 2014 in
- 15. Once bladder integrity is confirmed, pull the Needle upward to bring the Implant out through the abdominal exit site. Clamp the Implant just below the Needle. Cut the Implant between the connection to the Needle and the clamp.
- The procedure is now repeated on the patient's other side while repeating steps 9 15. NOTE: IN ORDER TO MINIMIZE THE RISK OF BLADDER INJURY, IT IS IMPORTANT THAT THE BLADDER BE DISPLACED TO THE CONTRALATERAL SIDE USING THE MANEUVERS OUTLINED IN STEP 10.
- 17. The ends of the implant are then pulled upward to bring the implant (sling) loosely, i.e., without tension, under the midurethra. Adjust the Implant so that leakage is reduced, allowing only a few drops of urinary leakage to occur under stress. For this, use patient feedback, i.e. coughing with a full bladder (approximately 300 mL).
- 18. Grasp the implant Sheaths that surround the implant with clamps, taking care not to grasp the implant. Then individually remove the implant Sheaths by gently politing up on the clamps, away from the abdomen, one at a time. To avoid putting tension on the implant, a blunt instrument (scissors or forcess) should be placed between the urethry and the implant during removal of the Implant Sheaths.
- 19. NOTE: Premature removal of the sleeth may make subsequent adjustments difficult.
- 20. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture the implant
- 21. Close the skin incisioris with sutgrear surgical skin adhesive.

 22. Empty the bladder Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE Mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregrancy

WARNINGS AND PRECAUTIONS

- Do not use SYNECARETVT procedure for patients who are on anti-
- coagulation therapy Do not use GYNECARE TVT procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT System before employing the GYNECARE TVT Device. It is important that the tape be located without tension under mid-urethra.
- Acceptable/surgical practice should be followed for the
- CYNECARE TYP procedure as well as for the management of contaminated or infected wounds.

 The GYNECARE TYP procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local contaminated or procedure of peadder will be provided to local contaminated or procedure of peadder will be provided to local contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as for the management of contaminated or procedure as well as well as well as the management of contaminated or procedure as well as well as the management of contaminated or procedure as well as well as the management of contaminated or procedure as well as well as the management of contaminated or procedure as well as well as the management of contaminated or procedure as well as well as the management of contaminated or procedure as well as well as well as the management of contaminated or procedure as well as anatomy and proper passage of needles will minimize risks.
- Retropublic bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from the hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The Rigid Catheter Guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- When removing the Rigid Catheter Guide, open the handle completely so that the catheter remains properly in place. Do not remove the plastic sheath until the tape has been
- properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.